REMARKS

Claims 1-14 are currently pending. Claims 1, 6, 7, and 13 have been amended, and new claims 15-16 have been added. Claim 1 has been amended to require the method of increasing lean body mass and reducing fat body mass in infants to include the step of identifying a need to increase lean body mass and reduce fat body mass in the infant, claims 6 and 7 have been amended to correct typographical errors, and claim 13 has been amended to more particularly claim the invention. New claims 15-16 have been added. Support for the amendment to claim 1 can be found throughout the specification, including, for example, on pages 1-2, page 9, lines 18-21, page 11, line 20 to page 12, line 6, and page 18, line 28 to page 20, line 13. Support for new claim 15 can be found in original claim 13 and in the specification on page 5, Table 1. Support for new claim 16 can be found in the specification page 11, lines 20-22, page 12, lines 29-32, and on page 15, lines 5-21. Applicants respectfully request reconsideration and allowance of all pending claims.

1. Rejection of the claims under 35 U.S.C. §112, Second Paragraph

Reconsideration is requested of the rejection of claim 1 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Specifically, the Office has objected to the phrase "reducing fat body mass" in the claim, stating that it is not clear if the

recited method reduces the existing fat in the newborn or the rate of the expected fat growth is to be reduced.

The second prong of 35 U.S.C. § 112, second paragraph requires that the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. M.P.E.P. § 2173.02. The Federal Circuit has held that this standard is met if "those skilled in the art would understand what is claimed when the claim is read in light of the specification." M.P.E.P. § 2173.02 citing Orthokinetics, Inc. v. Safety Travel Chairs, Inc. 1 USPQ 2d 1081, 1088 (Fed. Cir. 1986).

In the instant case, one skilled in the art would be able to ascertain the meaning of "reducing fat body mass" in light of the specification. Specifically, the specification states that infants fed formulas containing DHA and ARA had an increased lean body mass and a reduced fat body mass as compared to those fed a control formula (i.e., a formula that does not comprise a source of ARA and DHA), without an effect on the rate of overall growth of the infants.[1] The specification also describes using dual energy X-ray absorptiometry to measure the total body fat and total lean mass of the infants fed the control and DHA and ARA supplemented formulas.[2] In light of the disclosures in the specification, one skilled in the art would understand that the reference to "reducing fat body mass" in claim 1 is reference to

[1] *See* Specification at p. 2, lines 13-16, and page 18, lines 6-10.
[2] *See id.* at p. 15, lines 5-21. Body composition measurements for the infants participating in the study set forth in the Examples are set forth in Table 6 on page 25.

a reduction in fat body mass as compared to infants who are not subjected to the claimed method (e.g., infants not fed a nutritional formula comprising a source of DHA and ARA).

In light of the forgoing, applicants request the rejection of claim 1 under 35 U.C.C. 112, second paragraph be withdrawn.

2. Rejection of the Claims under 35 U.S.C. §102(b) over O'Connor, et al.

Reconsideration is requested of the rejection of claims 1-14 under 35 U.S.C. §102(b) as being anticipated by O'Connor, et al. (U.S. Application Publication No. 2002/0045660).

As amended, claim 1 is directed to a method of increasing lean body mass and reducing fat body mass in infants. The method comprises identifying a need to increase lean body mass and reduce fat body mass in the infant, and feeding the infant a nutritional formula comprising a source of DHA and ARA.

O'Connor, et al. is directed to methods for providing nutrition and for enhancing neurological development of preterm infants, and to nutritional compositions containing specified amounts of docosahexaenoic acid (DHA) and arachiodonic acid (ARA), as well as their precursor essential fatty acids alpha-linolenic and linoleic acids. The method comprises feeding infants nutrient-enriched formulas supplemented with long chain polyunsaturated fatty acid, including both DHA and ARA, for an extended feeding regimen, typically at least three months corrected age, and preferably to 6 or 12 months corrected age.

O'Connor, et al. state that the methods described therein do not result in growth inhibition of the infants, such as that previously observed when DHA without ARA was used, and also result in improved or enhanced neurological development, such as visual, motor, and language development.

Significantly, O'Connor, et al. fail to disclose or suggest identifying a need to increase lean body mass and reduce fat body mass in the infant, as required by amended claim 1. As noted above, O'Connor, et al. state that the ARA and DHA supplemented formulas described therein may improve or enhance neurological development, such as visual, motor, and language development, but do not disclose or suggest that such formulas have any effect on body composition, such as increasing lean body mass and reducing fat body mass.

As stated in MPEP §2131, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. Since O'Connor, et al. fail to disclose identifying a need to increase lean body mass and reduce fat body mass in an infant, and fail to disclose or suggest that the formulas disclosed therein have any affect on body mass, O'Connor, et al. fail to disclose each and every limitation of amended claim 1. As such, amended claim 1 is novel over the cited reference.

Claims 2-14 and new claims 15-16 depend from claim 1 and are thus patentable over O'Connor, et al. for the same reasons

as set forth above for claim 1, as well as for the additional elements they require.

Additionally, with regard to new claim 16, O'Connor, et al. fail to disclose or suggest evaluating the body composition of an infant after feeding the infant the formulas disclosed therein. Claim 16 is thus patentable over O'Connor, et al. for this additional reason.

3. Rejections of the Claims under 35 U.S.C. §102(b) over Koletzko

Reconsideration is requested of the rejection of claims 1, 5, and 11 under 35 U.S.C. §102(b) as being anticipated by Koletzko ("Fatty acids and early human growth," Am. J. Clin. Nutr., 2001, Vol. 73:671-2).

Koletzko describes various studies evaluating the relationship between long-chain polyunsaturated fatty acids, and early human growth. Koletzko notes that there is a possible relationship between the supply and metabolism of different fatty acids and early human growth. Koletzko further states that the provision of infant formulas with a balanced supply of dietary arachiodonic acid and docosahexaenoic acid in reasonable amounts and with adequate antioxidant protection, which is recommended by many experts worldwide, did not lead to poor growth or other adverse effects in several randomized clinical trials. Koletzko further notes that the quality of maternal dietary fat consumption before and during pregnancy and lactation is of considerable importance for infants.

Significantly, Koletzko fails to disclose or suggest identifying a need to increase lean body mass and reduce fat body mass in an infant, as required by amended claim 1. Nor does Koletzko recognize or suggest that formulas comprising ARA and DHA have any affect on body mass, much less increase lean body mass and reduce fat body mass. Rather, as noted above, Koletzko merely states that infant formulas with a balanced supply of dietary ARA and DHA did not lead to poor growth or other adverse effects in several randomized clinical studies.

Since Koletzko fails to disclose identifying a need to increase lean body mass and reduce fat body mass in an infant, and fails to disclose or suggest that the infant formulas comprising ARA and DHA have any affect on body mass, Koletzko fails to disclose each and every limitation of amended claim 1. As such, amended claim 1 is novel over the cited reference.

Claims 5 and 11 depend from claim 1 and are thus patentable over the cited reference for the same reasons as set forth above for claim 1 as well as for the additional elements they require.

4. Rejections of the Claims under 35 U.S.C. §102(b) over Innis, et al.

Reconsideration is requested of the rejection of claims 1, 5, and 10 under 35 U.S.C. §102(b) as being anticipated by Innis, et al. ("Docosahexaenoic acid and arachiodonic acid enhance growth with no adverse effects in preterm infants fed formula," J. Pediat., May 2002, Vol. 140, No. 5, pp. 547-54).

Innis, et al. describe a study testing the effects of DHA and ARA supplementation on growth or visual acuity of formula-fed premature infants. Specifically, the Innis, et al. study gave premature infants preterm formula with either no DHA or ARA (control), 0.15% energy DHA, or 0.14% DHA plus 0.27% ARA from single-cell triglycerides for at least 28 days, and then fed the infants term formula (with no DHA or ARA) to 57 weeks postmenstrual age. The results of the Innis, et al. study found that infants fed the DHA plus ARA formula gained weight significantly faster during preterm formula feeding than control infants, had weights and weight:length ratios not different from term breast-fed infants at 48 and 57 weeks PMA, and that providing DHA or DHA plus ARA during the preterm period had no effect on subsequent visual acuity or incidence of adverse events. Innis, et al. concluded that feeding DHA plus ARA from single-cell triglycerides enhances weight gain in formula-fed premature infants with no evidence of adverse effects.

Significantly, Innis, et al. fail to disclose or suggest identifying a need to increase lean body mass and reduce fat body mass in an infant, as required by amended claim 1. Nor do Innis, et al. recognize or suggest that formulas comprising ARA and DHA have any affect on body mass, much less increase lean body mass and reduce fat body mass. Rather, as noted above, Innis, et al. merely evaluated the effects of ARA and DHA supplemented formulas on the growth or visual acuity of formula-fed premature infants.

Since Innis, et al. fail to disclose identifying a need to increase lean body mass and reduce fat body mass in an infant, and fail to disclose or suggest that the infant formulas comprising ARA and DHA have any affect on body mass, Innis, et al. fail to disclose each and every limitation of amended claim 1. As such, amended claim 1 is novel over the cited reference.

Claims 5 and 10 depend from claim 1 and are thus patentable over the cited reference for the same reasons as set forth above for claim 1 as well as for the additional elements they require.

5. Rejection of the Claims under 35 U.S.C. §103(a)

Reconsideration is requested of the rejection of claims 1-14 under 35 U.S.C. §103(a) as being unpatentable over Innis, et al. ("Docosahexaenoic acid and arachiodonic acid enhance growth with no adverse effects in preterm infants fed formula," J. Pediat., May 2002, Vol. 140, No. 5, pp. 547-54) in view of Koletzko, et al. ("Physiological aspects of human milk lipids," Early Human Development, 2001, 65 Suppl.:S3-S18), and further in view of O'Connor, et al. (U.S. Patent Application No. 2002/0045660).

Innis, et al. and O'Connor, et al. are discussed above.

Koletzko, et al. discuss the physiological aspects of human milk lipids. Specifically, Koletzko, et al. state that human milk from healthy and well-nourished mothers is the preferred form of feeding for all healthy newborn infants, and discuss the general characteristics of human milk lipids and recent

knowledge on lactational physiology, composition, and functional aspects of human milk lipids. Koletzko, et al. state that the diet of lactating women influences, to some extent, the fatty acid composition of human milk lipids, and notes that biologically important long-chain polyunsaturated fatty acids (LC-PUFAs) in milk may originate from the maternal dietary intake, from maternal body stores, or from endogenous synthesis. Koletzko, et al. state that enrichment of infant formulas with LC-PUFA approximating the typical levels of human milk lipids has been considered to improve substrate supply to formula-fed babies, and that some studies in preterm infants have indicated functional effects of DHA supply on electroretinogram recordings, development of visual acuity, and performance in psychometric tests relative to infants fed formulas which contain linoleic acid and alpha-linolenic acid, but without preformed LC-PUFA.

Significantly, however, Koletzko, et al. fail to disclose or suggest identifying a need to increase lean body mass and reduce fat body mass in an infant, as required by amended claim 1. Nor do Koletzko, et al. recognize or suggest that formulas comprising ARA and DHA have any affect on body mass, much less increase lean body mass and reduce fat body mass. Rather, as noted above, Koletzko, et al. generally discuss the physiological aspects of human milk lipids, and note that enrichment of infant formulas with LC-PUFA approximating the typical levels of human milk lipids has been considered to improve substrate supply to formula-fed babies.

In order for the Office to show a *prima facie* case of obviousness, M.P.E.P. §2142 requires a clear articulation of the reasons why the claimed invention would have been obvious. Specifically, the Supreme Court in KSR International Co. v. Teleflex Inc., 550 U.S. ___, ___, 82 USPQ2d 1385, 1396 (2007) noted that the burden lies initially with the Office to provide an explicit analysis supporting a rejection under 35 U.S.C. 103. "[R]ejections on obviousness cannot be sustained with mere conclusory statements; instead, there must be some **articulated reasoning** with some **rational underpinning** to support the legal conclusion of obviousness."[3] The Court in *KSR International* further identified a number of rationales to support a conclusion of obviousness which are consistent with the proper "functional approach" to the determination of obviousness as laid down in Graham v. John Deere Co. (383 U.S. 1, 148 USPQ 459 (1966). Specifically, as previously required by the TSM (teaching, suggestion, motivation) approach to obviousness, one exemplary rationale indicated requires some teaching, suggestion, or motivation in the prior art that would have led one of ordinary skill to modify the prior art reference or to combine prior art reference teachings to arrive at the claimed invention.

Specifically, to reject a claim based on this rationale, the Office must articulate the following: (1) a finding that there was some teaching, suggestion, or motivation, either in the references themselves or in the knowledge generally

[3] *In re Kahn*, 441 F.3d 977, 988, 78 USPQ2d 1329, 1336 (Fed. Cir. 2006) (emphasis added).

available to one of ordinary skill in the art, to modify the reference or to combine reference teachings to arrive at each and every limitation of the claimed invention; (2) a finding that there was reasonable expectation of success; and (3) whatever additional findings based on the *Graham* factual inquiries may be necessary, in view of the facts of the case under consideration, to explain a conclusion of obviousness. The Office has failed to meet its burden under number (1) above, as the cited references fail to show each and every limitation of Applicants' invention and there is no apparent reason for one skilled in the art to modify the reference to arrive at each and every limitation. It simply would not have been obvious to one skilled in the art to arrive at Applicants' claimed combinations.

Initially, applicants note that none of the cited references disclose or suggest identifying a need to increase lean body mass and reduce fat body mass in an infant, as required by amended claim 1. Although the Innis, et al. and O'Connor, et al. references discuss the effects of ARA and DHA supplemented formulas, neither of these references, nor Koletzko, et al. disclose or suggest that infant formulas including both ARA and DHA have any effect on body composition, much less increase lean body mass and reduce fat body mass.

Nor is there apparent reason for one skilled in the art to modify the cited references or to combine reference teachings to arrive at the claimed limitation of identifying a need to increase lean body mass and reduce fat body mass in the infant.

As recognized by the Supreme Court in KSR International Co. v. Teleflex, Inc, while an obviousness determination is not a rigid formula, the TSM (teaching, suggestion, motivation) test captures a helpful insight: "A patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art. Although common sense directs [caution as to] a patent application that claims as innovation the combination of two known [elements] according to their established functions, it can be important to identify a reason that would have prompted a person of ordinary skill in the [art] to combine the elements in the way the claimed new invention does."[4] In the instant case, there is simply no apparent reason to modify or combine the teachings of O'Connor, et al., Innis, et al., and Koletzko, et al. to arrive at applicants' claimed method.

As previously discussed, none of the cited references disclose or suggest identifying a need to increase lean body mass and reduce fat body mass in an infant, as required by amended claim 1, or suggest that infant formulas including both ARA and DHA have any effect on body composition, much less increase lean body mass and reduce fat body mass. At best, O'Connor, et al. state that the ARA and DHA supplemented formulas described therein may improve or enhance neurological development, such as visual, motor, and language development, without findings of anthropometric growth faltering or inhibition. No where, however, is there any suggestion that the

[4] 2007 WL at 5.

formulas of O'Connor, et al. have any effect on body composition, such as increasing lean body mass and reducing fat body mass, or that a need to increase lean body mass and reduce fat body mass in an infant administered the O'Connor, et al. formulations should be identified. Similar to O'Connor, et al., the Innis, et al. reference evaluated the effects of ARA and DHA supplemented formulas on the growth or visual acuity of formula-fed premature infants, but fail to suggest that such formulas have any effect on body composition, such as increasing lean body mass and reducing fat body mass, or that a need to increase lean body mass and reduce fat body mass in an infant administered the formulas should be identified. Additionally, as previously noted, the Koletzko, et al. reference generally discusses the physiological aspects of human milk lipids, and notes that enrichment of infant formulas with LC-PUFA approximating the typical levels of human milk lipids has been considered to improve substrate supply to formula-fed babies. However, none of these references disclose or suggest that infant formulas including both ARA and DHA have any effect on body composition, much less increase lean body mass and reduce fat body mass. As such, why would one skilled in the art modify the method of O'Connor, et al. or Innis, et al. to include the step of identifying a need to increase lean body mass and reduce fat body mass in an infant as required in the method of Applicants' claim 1? There is simply no apparent reason to do so.

Accordingly, there is no articulated reason to combine or modify the teachings of the cited references to arrive at each

and every limitation of Applicants' claim 1. As such, claim 1 cannot be said to be obvious in view of the cited references.

As claims 2-14 and new claims 15-16 depend directly or indirectly from claim 1, claims 2-16 are patentable for the same reasons as claim 1, as well as for the additional elements they require.

Furthermore, with regard to new claim 16, applicants note that none of the cited references disclose evaluating body composition of an infant after feeding the infant a nutritional composition comprising ARA and DHA. Claim 16 is thus patentable over the cited references for this additional reason.

CONCLUSION

In light of the foregoing, Applicants request withdrawal of the rejections of claims 1-14 and allowance of all pending claims. The Commissioner is hereby authorized to charge the fee for the Request for Continued Examination filed herewith and any additional government fees which may be required to Deposit Account No. 01-2384.

Respectfully Submitted,

/Christopher M. Goff/

Christopher M. Goff, Reg. No. 41,785
ARMSTRONG TEASDALE LLP
One Metropolitan Square, 26th Floor
St. Louis, Missouri 63102
314-621-5070

CMG/LJH
By EFS